§ 526.1696d Penicillin G procaine-novobiocin for intramammary infusion.

(a) *Specifications*. For lactating cattle: each 10-milliliter dose contains 100,000 units of penicillin G procaine and 150 milligrams of novobiocin as novobiocin sodium. For dry cows: 200,000 units of penicillin G procaine and 400 milligrams of novobiocin as novobiocin sodium.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Lactating cows*—(i) *Amount*. 10 milliliters in each infected quarter after milking. Repeat once after 24 hours.

(ii) *Indications for use*. Treating lactating cows for mastitis caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(iii) *Limitations*. For udder instillation in lactating cattle only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. If redness, swelling, or abnormal milk persists, discontinue use and consult a veterinarian.

(2) *Dry cows*—(i) *Amount*. 10 milliliters in each quarter at time of drying off.

(ii) *Indications for use*. Treatment of subclinical mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae*.

(iii) *Limitations*. For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 526.1810 Pirlimycin.

(a) *Specifications*. Each 10-milliliter syringe contains 50 milligrams (mg) pirlimycin (as pirlimycin hydrochloride).

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.515 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. Infuse 50 mg into each infected quarter. Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

(2) *Indications for use*. For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *Staphylococcus* species such as *Staphylococcus aureus* and *Streptococcus* species such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations*. Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000; 73 FR 811, Jan. 4, 2008]

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 74 FR 6823, Feb. 11, 2009, unless otherwise noted.

§ 528.1070 Bc6 recombinant deoxyribonucleic acid construct.

(a) *Specifications and indications for use*. Five copies of a human Bc6 recombinant deoxyribonucleic acid (rDNA) construct located at the GTC 155–92 site in a specific hemizygous diploid line of dairy breeds of domestic goats (*Capra aegagrus hircus*) directing the expression of the human gene for antithrombin (which is intended for the treatment of humans) in the mammary gland of goats derived from lineage progenitor 155–92.

(b) *Sponsor*. See No. 042976 in §510.600 of this chapter.

(c) *Limitations*. Food or feed from GTC–155–92 goats is not permitted in the food or feed supply.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§529.40 Albuterol.

(a) *Specifications*. A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals*. See No. 000010 in §510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Amount*. Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use*. For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) *Limitations*. Not for use in horses intended for food.

[67 FR 7072, Feb. 15, 2002]

§529.56 Amikacin.

(a) *Specifications*. Each milliliter (mL) of solution contains 250 milligrams of amikacin as amikacin sulfate.

(b) *Sponsors*. See Nos. 000856 and 059130 in §510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 2 grams (8 mL) diluted with 200 mL of sterile physiological saline by intrauterine infusion daily for 3 consecutive days.

(2) *Indications for use*. For treating genital tract infections (endometritis, metritis, and pyometra) in mares caused by susceptible organisms including *Escherichia coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17339, Mar. 29, 2011]

§529.400 Chlorhexidine tablets and suspension.

(a) *Specification*. Each tablet and each 28-milliliter syringe of suspension contain 1 gram of chlorhexidine dihydrochloride.[1]

(b) *Sponsor*. See No. 000856 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet disolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.[1]

(2) *Indications for use*. For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.[1]

(3) *Limitations*. Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.